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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,103

11/12/2003

Douglas Craig Scott

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THE PROCTER & GAMBLE COMPANY
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,103	Applicant(s) SCOTT ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The response filed 11/06/09 has been entered.
2. Applicant's arguments filed 11/06/09 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-4 and 8-17 are pending in this office action.
5. The rejection of claim 14 under 35 U.S.C. 112, first paragraph (scope of enablement) is withdrawn because Applicant has cancelled the term preventing from the claim.
6. The rejection of claims 1-4, 8 and 10-17 under 35 U.S.C. 102(b) as being anticipated by Kiyoshige et al. (US 4,689,221) is withdrawn based on the amendment to the claims.

7. The rejection of claims 1-4 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiyoshige et al. (US 4,689,221) and Lawlor (US 6,706,256) is withdrawn because of the amendment to the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinberg et al. (US Patent 6,436,370) in view of Coll-Palagos et al. (US Patent 4,309,409).

Kleinberg teaches a dental oral composition (i.e., a chewing gum or a tablet) may comprise abrasives/polishing agents from 20-60%, a pH buffer (i.e., arginine bicarbonate which ensures pH neutrality), a surfactant (i.e., sodium lauryl sulfate) and an oral care active (i.e., a fluoride) as required by instant claim 1 (see col. 5, lines 29-33, col. 6, lines 16-20, 27-34, and 46-50) for the treatment of dental conditions such as dental sensitivity (as required by instant claim 14). Kleinberg also teaches that the oral active care is a fluoride ion source that provides approximately 10-1500 ppm of fluoride ion (see col. 6, lines 18-20, as required by instant claims 8 and 9). Since Kleinberg teaches a chewing gum, it is reasonable that the chewing gum is in a solid unit dosage form (as required by instant claim 10). With regards to instant claim 13, once the chewing gum is being placed in the oral cavity and chewed it intrinsically would buffer the oral cavity saliva to a pH of above neutrality as high as pH 9 (see col. 5, lines 29-34) wherein the buffer is an amino acid buffer (i.e., arginine bicarbonate, as required by instant claim 11, see col. 5, lines 29-34). It is reasonable that once the chewing gum comprising abrasives/polishing agents from 20-60% is chewed, intrinsically the polishing/abrasive agents will adhere to the teeth surface for a period of time (as required by instant claims 1, 3, 4, 13 and 16). Because Kleinberg does not teach their

oral composition as effervescent, it is reasonable to conclude that Kleinberg is a non-effervescent composition (i.e., as it relates to claim 1).

It should be noted that *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005) found that a claimed alloy was upheld as obvious over a prior art alloy that taught ranges of weight percentages overlapping, and in most instances completely encompassing, claimed ranges. See MPEP 2144.05.

However Kleinberg fails to specifically recite what comprises their abrasives or polishing agents. Coll-Palagos et al. is therefore introduced.

Coll-Palagos et al. teach an oral dentifrice formulation comprising an abrasive zinc oxide (i.e., water soluble) that may be present in the amount ranging from 40-67%, having a pH adjuster (i.e., phosphate buffer), a fluoride ion source (SnF_2KF), a surfactant (i.e., sodium lauryl sulfate) (as it relates to claims 1, 8, 10-11, see col.2, lines 1-6, 24-30 and col. 3, lines 38 and 55-62). With regards to the limitation of claims 1-2, 15 and 17 wherein the retentive agent has a water solubility of 1g/30 g at 25°C, this reasonably is an inherent property of the compound, because products of identical chemical composition can not have mutually exclusive properties (see MPEP 2112.01). With regards to instant claim 4, once the composition containing a pH adjuster, an active oral care, a surfactant and a water insoluble retentive agent (abrasive/polishing agents as known in the art) is placed in the mouth, reasonably 0.5%-20% by weight of the composition will deposit on the tooth surface. Because Coll-Palagos does not teach their oral composition as effervescent, it is reasonable to conclude that Coll-Palagos is a non-effervescent composition (i.e., as it relates to claim 1). Because, Coll-Palagos

teaches zinc oxide in their composition (i.e., identical compounds to the claimed invention), they intrinsically would have the same solubility of lg/30g at 25°C or less than lg/100g at 25°C. Therefore the limitations of claims 1- 2, 12 and 15-17 are met.

One of ordinary skill in the art would also expect the composition when chewed will be visible on 4-5 molars for 5-60 minutes because the same agents used in Coll-Palagos are the same recited in the claim 1.

However, Coll-Palagos fails to teach a solid dosage form.

Even though Kleinberg fails to recite the specific abrasive used in the composition, one of ordinary skill in the art would have been motivated to expand the oral solid chewable dentifrice composition taught by Kleinberg to include zinc oxide of Coll-Palagos because Kleinberg teaches generically that a dental oral composition (i.e., a chewing gum or a tablet) may comprise abrasives/polishing agents from 20-60%.

With regards to claim 12, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: “whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and

involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new”.

Moreover, the claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Nevertheless, in the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus because claim 12 is drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to this rejection under 35 USC 103.

Art Unit: 1618

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/18/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649